Chapter 1
INTRODUCTION

1.1 INTRODUCTION TO ANTI-MICROBIAL AGENTS

The Anti-Microbial agents are those medicinal agents & drug substances that are utilized in the therapy for the infectious diseases caused due to the micro-organisms like bacteria, virus, fungus, protozoa, parasites, and other organisms that causes illness & health problems in the individuals. These medicinal agents are widely used in the preventions as well as for the therapy of diseases in the body. They are also referred as chemotherapeutic agents.[1-2]

The anti-microbial agents are of different classes utilised in the treatment of the diseases, some of them which are applied topically for the prevention & and in the thaerapeutic- treatment of the diseases ailments infections are known as anti-septics, and which are utilised for the carnage of micro-orgs, on in-animate non living objects, surfaces are called as dis-infectants.[2] The other class of antimicrobials are known as antibiotics that are obtained from the other living organisms and that are used in the treatment of the diseases that are been generated by the other type of microbes. In the current scenario there are wide ranges variety of antibiotics are available for treatment of diseases caused by the microorganism. These are classified on the basis of which type of microorganisms they are able to stops attenuates the growth i.e. statics and kills destroys the organisms are known as cidals.[2]

The anti-microbials are classifies as on the basis of the ability to kill the type of organisms i.e. Antivirals, Anti-bacterials, Anti-protozoals, Anti-trypanosomal, Anthelmintics, Anti-parasitics. These medicinal agents are widely modernized in the therapy of the new diseases caused due to the micro-organisms. The newly modified synthesized drugs are been an-approved for the use purposes, and available into the market thearapeutics-for the treatment of the newer diseases as there is development of resistance of the drugs molecules that are not very effective for therapeutics's, purposes in treatment of the diseases. In the most of the current therapy-treatments of the diseases caused by the micro-organisms, there is application of combinational drug therapy which is more effective in the treatment of the diseases and more reliable approach in therapy rather than the single drug therapy.[2-3]

1.2 CLASSIFICATION OF ANTI-MICROBIAL AGENTS

1.2.1 Anti-Viral Drugs

The medicinal agents that are used in the therapy of the diseases that are induced by the infections due to viruses are termed as Anti-virals. These drugs are widely utilised in the treatment of DNA and RNA based pathogenic viruses that are infecting the host human body leading to diseased conditions.[4-5] The Anti-viral drugs are listed below:

- Respiratory Infections- Oseltamivir, Zanamavir, Dolutegravir, Ribavirin, Amantadine, Rimantadine, Maribavir, Molnupiravir,
- Hepatic Infections: Lamivudine, Stavudine, Telbivudine, Telaprevir, Teneofovir, Interferon, Boceprevir.
- Herpes and Cytomagalovirus Infections- Acyclovir, Cidofovir, Foscarnet, Gancyclovir, Penciclovir, Valacyclovir.
- HIV Infections: (NRTI) NucleosideNucleotide -Reverse- Trancriptase inhibitors-drug's:- Tenofovir, Zidovudine, Lamivudine, Stavidine, Abacavir, Didanosine, Zalcitabine, Emtricitabine, Didanosine.
- HIV Infections: (NNRTI) Non-Nucleoside-Nucleotide Reverse Trancriptase-inhibitors- Delaviridine, Efavirenz, -Etravirine-Nevirapine,-Rilpivirine.
- HIV Infections: Protease-enzyme-Inhibitors-drug's:- Atazanavir, --Darunavir-Fosamprenavir,-Indinavir-drug-,Ritonavir,-lopinravavir,-Saquinavavir, Amprenavir,
- HIV – Entry Inhibitors-enzyme-class-drugs-- Enfuvirtide,-Maraviroc
- HIV- Integrase Inhibitors- Dolutegavir, Elvitegravir, Raltegravir
- HIV- Combinations – Lamivudine + Abacavir, Emtricitabine + tenofovir, Zidovudine + Lamivudine, Rilpivirine + Tenofovir + Emtricitabine, Zidovudine + Lamivudine + Abacavir, Eltegravir + Cobicistat + tenofovir + Emtricitabine

1.2.2 Anti-Bacterial Drugs

The Anti-Bacterial class of drugs are the medicinal agents that are used in the infectious diseases caused by the different types of bacterial infections in the human body. The pathogenic bacteria are of different types gram +ve, gram –ve, cocci, rod shaped and other types that infects the host cells into the human body and

multiplication & growth of bacterial cells in the human body leads to the diseased conditions.[6] The anti-bacterial drugs are classified as following:

- Cell-Wall Synthesis Inhibitors :

  Penicillins:- Amoxicillin, Ampicillin, Dicloxacillin, Penicillin-G, Penicillin V, Oxaclllin, Nafcillin, Oxacillin, Methicillin, Carbenicillin,

  Cephalosporins:- Cefaclor, Cefexime, Cefadroxil, Cefpodoxime, Cefuroxime, Cephalexin, Cefoxitin, Cefazolin,

  1st Generation Cephalosporins- Cefazolin, Cefadroxil, Cephalexin, Cephradine.

  2nd Generation Cephalosporins- Cefaclor, Cefoxitin, Cefuroxime, Cefamandole,

  3rd Generation Cephalosporins- Cefexime, Cefoperazone, Cefotaxime, Ceftazidime, Ceftriaxone, Moxalactam,

  4th Generation Cephalosporins- Cefclidine, Maxipime, Cefiderocol, Ceflupren am, Cefpirome, Cefoselis,
- B-Lactamase-enzyme-Inhibitors-class-of-drugs:- Clavulanicacid,-Sulbactam, --Tazobactam,
- Carbapenem's-drug-classes-:- Doripenem, Ertapenem, Imipenem's-, --Cilastatin,-Meropenem.
- Protein-Synthesis Inhibitors :

  Aminoglycosides :- Gentamycin, Kanamycin, Streptomycin, Neomycin, Tobramycin,

  Tetracyclines:- Doxicycline, Minocycline, Teracylcine, Demeclocycline, Macrolides:- Erythromycin, Azithromycin, Clarithromycin, Telithromycin, Glycycline- Tigecycline, Lincosamide- Clindamycin, MacroCyclic- Fidaxomicin, Oxazolidinones- Linezolid,
- Fluroquinolones:- Gatifloxacin, Moxifloxacin, Norfloxacin, Ciprofloxacin, Levofloxacin, Ofloxacin, Nalidixic acid,
- Folate Inhibitors- Mafenide, , Silver sulfadiazine, Sulfasalazine, Pyrimethamine, Trimethorpim, Cotrimoxazole (Trimethoprim + Sulfamethoxazole)
- Urinary tract Infections- Nitrofurantoin, Methenamine,
- Others:- Chloramphenicol, Quinupristin, Dalfopristin.

1.2.3 Anti-Fungal Drugs

The drugs which are utilised in the therapy the mainly adopted-in-treatment among the of the infectious-causing-diseases caused by the fungus are called as anti-fungal drugs.[7-8]

- Azoles- Ketoconazole, Miconazole, Voriconazole, Itraconazole, Clotrimazole, Sertaconazole, Oxiconazole.
- Polyenes- Amphotericin B, Nystatin, Hamycin, Natamycin.
- Allyl-amine- Terbinafine, Benzofuran- Griseofulvin
- Anti-metabolite- Flucytosine
- Topical- Tolnaftate, Benzoic acid, Quiniodochlor, Cicloprox olamine,

1.2.4 Anti-Protozoal Drugs

The drugs that are used in the treatment of diseases caused due to protozoa, amoeba, trypanozoma, leshmania, are called as anti-protozoal drugs[9-13]

- Anti-Amoebiasis- Tinidazole, Metronidazole, Paromomycin, Dehydroemetine, Chloroquine, Diloxanide
- Anti-Malarial- Chloroquine, Mefloquine, Primaquine, Proguanil, Pyremathamine, Artemether, Lumefantrine, Quinine, Quinidine,
- Trypanosomiasis- Nitfurtimox, Pentamidine, Suramin, Eflornithine, Benzdidazole, Fexinidazole
- Leshmainiasis- Miltefosine, Sodium stibogluconate
- Giardiasis- Nitazoxanide, Tinidazole, Metronidazole.

1.2.5 Antihelmintic Drugs

The drugs that are used in the diseases caused by the helminthes, worms in the body that are called as antihemintic or anthelmintics.

Mebendazole, Albendazole, Niclosamide, Praziquantel, Thiabendazole, Ivermectin, Diethylcarbamazine, Pyrantel pamoate

1.3 INTRODUCTION TO ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

It is an procedure in which the different methods for the testing and analysis are developed discovered invented ,that are been made in majorly as in for the lab-industrial-testing & analysis drug substances active pure api-pharmaceutical ingredients in pure form and in the different types of pharmaceutical dosage forms.

The analytical method development is a procedure for generating different methodologies, processes, protocols, materials, protocols, generated for the testing analysis measurement of the analytes- i.e. drugs, api, solutes, impurities, excipients, preservatives and additives in pharmaceutical drug substances.

The Validation of the Analytical method procedures is the course of action in which it justifies the practical ability of a analytical method which meets the necessities to perform the laboratory analytical studies that can be applied for the purpose for which it has been produced.

The Identification & quantification of drugs , medicine, API ,impurities is an important crucial-critica—important processes-task in pharmaceutical process development for quality-regulations and safety-regulations purposes is made efective. The incidence-occurance-presence of, these unnecessary-undesired foreign substances chemicals-products., even in small quantity, amounts may influence-degenerate-deteriorate's, in the drug-medicinal agents-efficacy and safety-patient compliance's for of the pharmaceutical products, and hence need for into the criteria for generating., Various analytical methodologies-techniques-procedures., are utilized, employed-made,in the for the determination, analysis of major drugs-related components in Newly-approved-pharmaceutical dosage forms. There is a great-immense and severe, -need for development of newer analytical methods for analysis-testing's & validation for quality evaluation-assesment-estimation's-testings., of new emerging drugs.

1.3.1 The steps involved in method development and method validation

- It includes-involves the plans made for definitions, Background-information's data-gathering, drug profile, review literature, Selection of samples and analytes. Selection of the suitable method for the analytes on the basis of the physical, chemical nature of chemical substance and its pharmaceutical dosage forms. Specific procedure, tests & pretreatments for samples if required.
- Review of methods of analysis is required for, if present for the chemical

substance, Laboratory Lab-analytical- method development-process, it includes., involves the generation of the various stages namely- sample preparation standards-samples of the drugs, specific analytical method, extraction & isolation, identification, purification, Instrument selection, optimization, detection, data-processing-analysing-testing of data, Generation of the major testing procedure's.

- The developed method experimentally practically can should be effortless to validate, it should, have been to be developed along with the major goal's with the goal-aims to rapidly test into the different-types of pre-clinical samples that are adopted, formulation pro-totypes-pre-formulations, different types of pharmaceutical formulations as well as in commercial marketed samples.

1.3.2 Need for the Method Development & Validation in Pharmaceuticals

- The importance for the method development-procedures-methologies and the validation is for in assuring the quality of the product, as along with the well as in the Analysis of Active drug-medicinal's, molecules substances & Drug product, also it is very much essential for the recently approved drug Molecules, Phyto-chemical and can be done in the herbal phyto-chemical products
- Method development is applied in the Impurity profiling, Residual microanalysis, Component of interest in matrices in the dosage forms.
- The method development validations are applied in the to achieve, the criteria's for the- the acceptance products in accordance guided by international agencies, it's also a one of the important deliberately performed, mandatory requirement for registration of any pharmaceutical product, Validation of the analytical procedures not only it would improve the processes-procedures-methods, but also confirms that, processes- procedures adopted are properly-accurately been generated and developed, those which are efficient in analysis, as well as it deepens the perceptive of process and reduces the risk's in the, troubles, It decreases-reduces., the risk of defect-impurities- costs,- It decreases-reduces, removes errors's into the risk of regulatory-noncompliance, A effusive-whole totally validated processes., may require less-decreased level's in-process controls- ipqc and end product –

final-quality,testing, Related-substances, drug, -products-impurities, related-products, by-products, -impurities., that are the, undesired-foreign substances, unwanted- that present or remain-hang about- along-with the active ap--pharmaceutical drug products., that has been or may might been during develop along with the substances, during short or long-term, stability testing, or can might be generated autonomously into the, develop during preparations-compunding-formulation or upon long term storage-aging duration of both API-pure-drug-forms, and of for the formulated-APIs into the to medicines, The Validation of the developed analytical methods processes are a significant criteria which supports the method to be, accordance with the parameters of precise and accurate for the purpose of testing-quality-control and the analysis.[14-21]

- It includes validation parameters carried out per in accordance criteria of ICH guideline Q2-R1 like-Accuracy, Precision, Repeatability, Intraday precision, Interday Precision, Linearity, Range, -Specificity, Recovery, Ruggedness, Robustness, LOD,.- Limit of Detection., and the other one is the LOQ:-Limit of Quantification.[21-27]

1.3.3 Need for the Stability Indicating Method Development & Assay Method SIAM New Drug Substances and Products

- The Stability-method is applied for the Non specificity of the Assay -Procedures, and are essentials for the New Drug Molecule's- to detect the unknown degradation products present, identifying the known or the unknown impurities, byproducts and various types of intermediates.
- It is most essential for the New Dosage Forms- detecting the instability of API, Incompatibility with other active and inactives, The studies are performed for the elucidation intrinsic, -inherented,- stability distinctiveness of different the of drug substances. Majorly, these types of the, testing-analysis are one of the is part of the development-plan's approaches and strategy and therefore it is essentially carried performed made out conceded normally together to be analysed approaches- carried out as in under into the strong-more severe stress forced degradations conditions, that are been adopted into the usable purposes as in those used along in the for accelerated tests. The stress testing is performed and conducted to mainly provide data on forced

decomposition of the drug substances, pure forms and drug- products and decomposition as well as degradations of for the drug substance. The guideline Q1A (R2) Stability Testing Process of New Drug Substances and Products.[27]

- The Stress-testing -forced degradation studies are -procedures, methods that are done conceded outon a individual single batch of the drug substance. In method includes temperature dependent thermal temperatures effects (in 10°C increment interval are performed for degradation's of drug substances and for the, humidity 75% RH or greater is applied and along with he , oxidation, and photolysis degradation study is done on the on the drug substance.
- It should be carried out to evaluate the susceptibility of the drug substance & drug products to hydrolysis across a depending upon a various pH values of the solutions and the suspension forms. Photostability testing should be an integral part of stress testing.
- ICH guideline – code -Q1-B on the photo stability testing defines the requirements as follows:
- The Forced degradation by the photolytic-degradation is performed on the drug substances and drug products to analyse the photosensitivity of them for development criteria and for the degradation path study elucidation can be evaluated..

1.3.4 Selection of the Spectroscopic & Chromatographic Methods

- The methods are simple, rapid and reproducible during the analysis.
- High sensitivity & High Performance as compared to conventional methods.
- Rapid process, hence time saving in comparison to conventional methods.
- Has a high resolution & separation capacity.
- Accuracy & Precision in the developed methods.
- Variety of polar, non-polar molecules can be separated & analyzed.
- Ease of recovery of analyzed samples can be easily done.
- Utilized most frequently by the industries, research, academics for qualitative & quantitative analysis.
- Can be applied for both analytical testing detections & preparative purposes.
- Cost effective-economic methods as compared to other hyphenated techniques.

1.3.5 Validation Parameters for Analytical Method

1.3.5.1 Accuracy

Accuracy is one of the important validation parameter which describes the trueness-exactness of the test results in accordance with the true values. The developed method must be validated for the accuracy parameter for the exact measurements of the analytes present in the samples. Majorly the accuracy is measured in the terms of recovery studies that are performed by adding deliberate amount of the drug substances that are must be recovered from the samples, which justifies the accurate measurements are been performed during analysis.

1.3.5.2 Selectivity & Specificity

Selectivity and the specificity parameters are adopted in for the selective detection of the particular analyte which are in the matrix or along with other substances without any interventions. Selectivity is a type of a qualitative determination of analytes, while the specificity is applied for both qualitative as well as quantitative estimations. The developed method must be selective and highly specific for the analyte for which the method is intended to use, even in presence of impurities or any other degraded products, additives, excipients, reagents or other substances.

1.3.5.3 Linearity

The linearity parameter is utilised in validation to rationalize the developed-analytical-procedures and methods are able to detect the analyte in a particular range of concentrations with a linear response signal with reference to concentrations. It he ability of the method to measure the linear results proportional to the amount concentrations of the analytes in the samples. It can be studies by preparing the samples of various concentrations and generating a plot of linear relationship of signal vs concentrations.

1.3.5.4 Range

The range parameter is generally obtained during the linearity studies performed, it provides the interval in between the upper higher amounts of conc. of analytes and lower less amounts conc. of analytes that, are to be measured during analysis along with accuracy and precision. The range parameter establishes a particular concentration level intervals lower to higher concentrations in which a particular analytical method can detect quantitatively the amount of analytes along with linear responses.

1.3.5.5 Precision

The precision validation parameter is adopted to demonstrate the nearness-closeness to the values of concentrations measured by the analytical method. Precision helps in determining that the analytes measured during analysis by the method are close to the value & repetitively can be measured with same analytical method that is developed. It is measures as Interday precision, Intraday precision, Repeatability and reproducibility.

1.3.5.6 Limit of Detection LOD

The LOD parameter is been implicated to study the least lowest amount-quantity of the analyte/drugs that to can be measured/detected qualitatively during analysis by help of the developed analytical method with accuracy & precision. Primarily, it is determined by visual estimations, or on the bases of signal to noise ratio with reference to blank samples. It can also be calculated from standard deviation & slope of the responses obtained.

1.3.5.7 Limit of Quantification LOQ

The quantitation limit for any drug substances and the analyte's that are been present in the samples which are analysed by help of analytical method, determines the least-minimum amount of analyte to be quantitatively analysed. The minimum amount of analyte to be measured in samples, matrices, degradants, impurities and other products along with the quantitative estimations with accuracy & precision.

1.3.5.8 System Suitability

It is an essential parameter for instrumental approach in analysis, where the analytical procedure is able to evaluate equipments, analysis approach, samples, electronics, instrumental parameters adjusted for resolution & reproducibility of results.

1.4 INTRODUCTION TO INSTRUMENTAL ANALYTICAL APPROACH

1.4.1 UV-Visible Spectroscopy

The UV-Visible Spectroscopy method utilised for the sample atoms/molecules which are possessing sigma, pi or n electrons, that can be excited by the UV-Visible electromagnetic radiation incident on them, resulting in the absorption & emission of the radiation from the sample that is qualitatively & quantitatively measured. For a

particular substances the graph of absorption or the emission of radiation vs frequency/wavelength can be plotted, which is a characteristic for the specific analyte. The intensity of the absorption/emission at a particular wavelength for any sample analyte can be obtained, and the same can be used for the qualitative and quantitative estimations.

The instrumentation involves a light source, monochromater-filters-grating, sample holders-cuvettes, detectors-photocell, photoelectric detectors, and readout device. The sample, the reference standard and blank solvents are utilised in the analysis purpose. The blank absorbance of the solvent/medium are first scanned in the UV-Visible region and the baseline to zero absorbance is set, and then the relative absorbances of the sample & reference standard are taken. The absorbance /emission are taken at a wavelength which shows maximum absorbance/emission. The calibration curve of standard helps to calculate the unknown concentration of sample.

Various techniques & modifications are adopted in the UV-Visible spectrophotometric method of analysis, in which the combined analytes samples are been analysed through the different techniques like derivative spectroscopic method, absorbance ratio method, absorbance correction method, simultaneous equation methods are been adopted for multi-component analysis. The automated software systems helps in modifications that eliminates interferences, as well as can accurately analyse the principal component analytes through different methods. [28-30]

1.4.2 FTIR- Spectroscopy

The FTIR- Fourier-Transform-Infrared spectroscopy is utilised for the infrared absorption/emission spectra from a analyte. The infrared electromagnetic radiation source is utilised and incident on the sample analyte that induces the vibrational-oscillatory motion in the atoms/molecules of the sample analyte that generates a absorption/emission spectrum characteristic of a particular atoms or group of atoms and functional groups. For a particular atoms/functional groups it has a specific wavelength wave-number frequency for absorption/transmission which is called as finger print region, hence a typical characteristic peak signal are obtained for every functional groups. This helps in the qualitative analysis identification of the type of the molecules or a compound. It aids in the identification of unknown materials, impurity, quality of sample as well as determines the components in a matrix.

The instrumentation includes IR-radiation source, set of reflective mirrors, interferometer, beam splitters, probe-sample holder, lens, detector and output reading device. It is utilised in the identification of organic compounds, medicinal agents, structural elucidation, isomerism's, complex compound determinations, detection of impurities as well as study of conformational analysis. Along with the hyphenation with chromatography and thermo-gravimetric analysis it can be used as a fine detection technique.[30]

1.4.3 HPLC High Performance Liquid Chromatography

The modern liquid chromatography approaches are been utilised in the analysis of the pharmaceutical substances. Currently, HPLC-High Performance Liquid Chromatography method's been adopted with a higher efficiency of separations by using various sophisticated and accurate robust instrumental approaches. It involves the use of separating columns stationary phase which is made of packing adsorbing agents helps to separate the analytes in very minute quantities. The polar as well as non polar stationary phase columns are used along with the various mixtures of mobile phase solvent systems buffer solutions of variable pH and polarity are utilised for the separation, isolation and quantitative as well as qualitative estimations of the substances.

Currently, the reverse phase chromatographic methods are efficiently used in the analysis-testing-quality control for of the drug substances and drug products, including use of non polar stationary phase having silica based packing adsorbents along with hydrocarbon silane compounds, and use of polar organic, aqueous solvents in the mobile phases. The high pressurized pump systems along with isocratic & gradient flow are used for efficient separations. The automated instrumental HPLC systems aids additional facility for error free analysis and quick-rapid testing procedures can be made for the research, academics and industrial use.

Most extensive use of the HPLC analysis methods are been made for % purity testing, assay analysis, degradation studies, stability testing, impurity analysis, separation-purification-isolation, preparative and analytical testing purposes. Even currently the dissolution testing of the drugs substances and solid oral dosage forms are been made analysis quantitatively by combining with the HPLC methods.[31-37]

1.4.4 In-Vitro Dissolution studies

For the pharmaceutical dosage forms, the drug solubility and the permeability analysis is one of the important criteria. The drug release profile study from the dosage from is an important criteria for efficacy-affinity and its effectiveness must be determined. Most of the solid oral dosage forms are analysed by the in-vitro or in-vivo drug dissolution release profile studies, while the in-vitro is helpful to study release profile in laboratory by analytical methods without any animal or human trials. The simulated gastric, intestinal, buffer medium, blood plasma and in the other body fluids can be utilised as a medium for drug release , and the % release profile can be analysed by dissolution testing apparatus by combining with uv-spectrophotometric & HPLC chromatographic methods for the qualitative and as well as into the quantitative estimations of the drug substances-drug products.

The In-Vitro Dissolution studies helps in ensuring the quality-stability of drug products, evaluates bioavailability, uniformity of drug release batch to batch in dosage forms, therapeutic efficacy of the drug is analysed. In the product development qc quality control research the dissolution testing is an important tool. The dissolution apparatus paddle and basket are widely used for tablet capsule and other solid oral dosage forms , and the drug release in the solutions are analysed by spectroscopic and chromatographic methods. In the analytical method development, the developed method can be utilised to the dissolution drug release profile studies from the dosage forms.[38-41]

1.5 DRUGS AND FOMULATIONS SELECTED FOR THE ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

- DELSTRIGO™ Combination: Doravirine Delstrigo™ (Doravirine drugs 100mg and the Lamivudine drug 300mg and the Tenofovir Disoproxil Fumarate drug 300mg) , by Merck Sharp & Dohme B.V.
- CABENUVA™ (Cabotegravir drug 200 mg /1 mL + Rilpivirine drug 300 mg / 1mL) ER-Injection , by ViiV Healthcare, joint venture of GlaxoSmithKline (GSK), Pfizer and Shionogi developed.
- CABENUVA 400-mg / 600-mg Kit ER-Injection. single-dosed vial's of 400 mg / 2 mL (200 mg / 1mL) of drug cabotegravir & single - dosed vial's of 600 mg/ 2 mL (300 mg/1mL) of drug rilpivirine.
- DOLUVIR™ 50 Hetero contains 50mg Dolutegravir, TENVIR™ 300 Cipla contains 300mg Tenofovir and EDURANT™ Jansen contains Rilpivirine 25mg
- WINTHROP™ 600 conatains 600mg Fexinidazole oral tablet dosage form by DNDi and Sanofi.
- LIVTENCITY™ 200 mg Maribavir oral tablet form, by Takeda pharma
- MOVFOR™ 200 mg Molnupiravir oral Capsule form by Heterolabs
- VOQUEZNA Triple Pak™ Phathom Pharma, containing Amoxicillin 500 mg capsules along with the drug Clarithromycin 500 mg tablets and Vonoprazan 20 mg tablets

The Main Objective is to Develop Analytical Methods for Following Antimicrobial Agents:

1. HPLC METHOD DEVELOPMENT AND VALIDATION FOR DELSTRIGO COMBINATION
2. STABILITY INDICATING HPLC DEVELOPMENT AND VALIDATION FOR DELSTRIGO COMBINATION
3. HPLC METHOD DEVELOPMENT AND VALIDATION FOR CABOTEGRAVIR AND RILPIVIRINE
4. STABILITY INDICATING HPLC METHOD DEVELOPMENT AND VALIDATION FOR CABOTEGRAVIR AND RILPIVIRINE

5. HPLC METHOD DEVELOPMENT AND VALIDATION FOR DOLUTEGRAVIR, TENOFOVIR AND RILPIVIRINE
6. STABILITY HPLC METHOD DEVELOPMENT AND VALIDATION FOR DOLUTEGRAVIR, TENOFOVIR AND RILPIVIRINE
7. HPLC METHOD DEVELOPMENT AND VALIDATION FOR FEXINIDAZOLE
8. STABILITY INDICATING HPLC METHOD DEVELOPMENT AND VALIDATION FOR FEXINIDAZOLE
9. HPLC METHOD DEVELOPMENT AND VALIDATION FOR MARIBAVIR
10. STABILITY INDICATING HPLC METHOD DEVELOPMENT AND VALIDATION FOR MARIBAVIR
11. HPLC METHOD DEVELOPMENT AND VALIDATION FOR MOLNUPIRAVIR
12. STABILITY INDICATING HPLC METHOD DEVELOPMENT AND VALIDATION FOR MOLNUPIRAVIR
13. HPLC METHOD DEVELOPMENT AND VALIDATION FOR VOQUEZNA COMBINATION- AMOXICILLIN, CLARITHROMYCIN AND VONOPRAZAN
14. STABLITY HPLC METHOD DEVELOPMENT AND VALIDATION FOR VOQUEZNA COMBINATION- AMOXICILLIN, CLARITHROMYCIN AND VONOPRAZAN